DETAILED ACTION

Response to Amendment/Arguments

No amendments to the claims were filed. However, it is acknowledged that Applicants have stated on page 1 of the response filed February 25, 2010 that claims 2, 6 and 10 are being cancelled by said response. However, Applicants have not filed an amendment to the claims. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered). See MPEP Chapter 700. Applicant must file an appropriate amendment to the claims, canceling claims 2, 6 and 10.

However, in light of Applicant's statement on page 1 of the response filed February 25, 2010 and for the sake of advancing prosecution, claims 2, 6 and 10 are cancelled and claims 1, 3-5 and 7-9 are currently pending and presented for examination. Due to the cancellation of claim 10, the previous rejection under 35 USC 112 is withdrawn.

Applicant's arguments filed February 25, 2010 regarding the previous rejection under 35 USC 103 have been fully considered but they are not persuasive.

Applicants argue that the cited prior art references are not in the same fields and as such anyone with ordinary skill in both of those unrelated arts would not make an obvious connection between lucidity and cholinergic drugs.

This argument is found not persuasive as both cited prior art references deal in the area of sleep. Furthermore, both recited prior art references specifically discuss rapid eye movement (REM) sleep. Thus an ordinary skilled artisan would make an obvious connection between both references as both references provide teachings about REM sleep and methods of detecting and/or enhancing REM sleep.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants further argue that while it may be obvious that anything that alters REM sleep may influence dreaming, there is nothing in the recited prior art teachings that suggest altering or enhancing REM would specifically enhance or alter dream lucidity.

This argument is found not persuasive since Raynie et al. teach that the ability to experience lucid dreaming occurs during REM sleep and Hedner et al. teach that the administration of acetylcholinesterase inhibitors produce an increase in REM sleep and a shortening of the latency from sleep onset to the first episode of REM sleep. Thus, it would be obvious to one of ordinary skill in the art that if the period of time during REM sleep is increased, the period of time in which lucid dreaming could occur would also be increased. Thus by increasing REM sleep it would be obvious that the amount of lucid dreaming would also be increased and therefore enhancing the frequency and intensity of lucid dreaming is rendered obvious. Furthermore, since lucid dreaming occurs during REM, the more time that is spent in REM increases the chance of more lucid dreaming and thus more lucid dreaming is equivalent to the enhancement of the frequency and intensity of lucid dreams.

Applicants further argue that it was necessary for the applicant to specifically perform the clinical research in order to determine a causal relationship between acetylcholinesterase and lucidity frequency or intensity. Furthermore, the Applicants argue that until they did the original research to demonstrate this relationship, no such connection was ever suggested by any patent or other art.

These arguments are found not persuasive because the Examiner has presented a prima facie case of obviousness and this argument fails to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicants further argue that the instant invention has been cited by many sources, including books dedicated to dream influencing substances. Applicants further argue that the lack of implementation prior to the invention's publication mitigates any suggestion of obviousness as the invention would have already been implemented. Applicants further argue that Brilliant Brands LLC has introduced the instant invention in the marketplace and thus in this sense has achieved a level of commercial success.

These arguments are found not persuasive because the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP § 2145 generally for case law pertinent to the consideration of applicant's rebuttal arguments.

Furthermore, in order to prove the claimed subject matter solved a problem that was long standing in the art there must be a showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there must be evidence showing that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04.

Applicants declaration filed February 25, 2010 is found not persuasive. More than the mere fact of copying is necessary to make that action significant because copying may be attributable to other factors such as a lack of concern for patent property or contempt for the patentees ability to enforce the patent. Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 226 USPQ 881(Fed. Cir. 1985). Furthermore, alleged copying is not persuasive of nonobviousness when the copy is not identical to the claimed product, and the other manufacturer had not expended great effort to develop its own solution. Pentec, Inc. v. Graphic Controls Corp., 776 F.2d 309, 227 USPQ 766 (Fed. Cir. 1985). See also Vandenberg v. Dairy Equipment Co., 740 F.2d 1560, 1568, 224 USPQ 195, 199 (Fed. Cir. 1984) (evidence of copying not found persuasive of nonobviousness). In the instant case, Applicants alleged infringers teach a combination of nutrients including galanthamine, choline, vitamin B5 and melatonin to encourage lucid dreaming whereas the claims of the instant application are drawn to an acetylcholine esterase inhibitor such as galantamine to enhance the frequency and intensity of lucidity in dreaming. Thus the alleged copy is not identical to the claimed method.

Thus for reasons of record and for the reasons presented above, the previous rejections under 35 USC 103 are hereby maintained and reproduced below. This action is made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raynie et al. U.S. Patent No. 5,551,879 in view of Hedner et al. U.S. Patent No. 6,034,117.

Raynie et al. teach that lucid dreaming is the ability to be aware of the experience of dreaming, while in a dream state and that this phenomenon occurs when an individual in the dream state, and without awakening, realizes that he/she is dreaming (see column 1 lines 12-16). Raynie et al. teach that becoming lucid while dreaming is in itself an exhilarating experience and may be used for educational purposes and that the problem with lucidity is that it often occurs on its own with little or no means of consciously inducing or controlling this state while dreaming (see column 1 lines 44-48). Raynie et al. teach an apparatus for the detection of rapid eye movement (REM) during sleep to help induce lucid dreaming (see column 1 lines 36-38). Raynie et al. further teach that the REM state of sleep offers a benefit for learning to become lucid in REM sleep (see column 1 lines 52-54). Thus Raynie et al. teach that the ability to experience lucid dreaming occurs during REM sleep.

Raynie et al. further teach that different methods and techniques have been developed to help the induction of lucid dreaming including chemical compounds like DMAE (2-dimethylaminoethanol) which hold the user at a higher level of consciousness while sleeping (see column 1 line 60 to column 2 line 6). Raynie et al. teach an apparatus or device that helps to induce lucid dreaming, equipped with a REM detector which checks for REM about once every minute and is thus less likely to miss REM activity (see column 3 lines 12-14).

Raynie et al. do not teach the administration of an acetylcholinesterase inhibitor to enhance the frequency and intensity of lucidity in dreaming.

Hedner et al. teach that central nervous acetylcholinergic mechanisms are intimately involved in the regulation of wakefulness and sleep, particularly rapid eye movement (REM) sleep (see column 3 lines 10-13). Hedner et al. further teach that systemic administration of acetylcholinesterase inhibitors in humans produce an increase in REM sleep and a shortening of the latency from sleep onset to the first episode of REM sleep (see column 3 lines 19-21). Hedner et al. further teach numerous examples of acetylcholinesterase inhibitors such as physostigmine, velnacrine, huperzine A, etc. (see column 3 line 45 to column 5 line 8).

Accordingly, one of ordinary skill in the art at the time of the instant invention would have found it obvious to combine the teachings of Raynie et al., which teach that the ability to experience lucid dreaming occurs during REM sleep, with the teachings of Hedner et al., which teach that the administration of acetylcholinesterase inhibitors produce an increase in REM sleep and a shortening of the latency from sleep onset to

the first episode of REM sleep. Thus, since acetylcholinesterase inhibitors produce an increase in REM sleep and a shortening of the latency from sleep onset to the first episode of REM sleep, it would be obvious to one of ordinary skill in the art that the administration of an acetylcholinesterase inhibitor would enhance the frequency and intensity of lucidity in dreaming since the period in which lucidity in dreaming occurs, REM sleep, would be increased and the amount of time needed to reach REM sleep would be shortened, thus increasing the frequency of REM sleep episodes. Furthermore, it would be obvious to one of ordinary skill in the art that if the period of time during REM sleep is increased, the period of time of lucid dreaming would also be increased, resulting in longer or more frequent lucid dreams thus increasing the intensity of the lucid dream.

Regarding claim 3, it would be obvious to administer the drug at bedtime since lucidity in dreaming occurs during sleep and specifically during REM sleep. Regarding claim 4, it would be obvious to combine an acetylcholine esterase inhibitor with a device as claimed by Raynie et al. that enhances lucidity in the dream state that occurs during REM sleep since the device enhances lucidity during REM and the acetylcholinesterase inhibitor will increase REM thus increasing the frequency and intensity of lucid dreams. Claim 10 is rendered obvious based upon the rationale presented above that if REM sleep is increased by acetylcholinesterase inhibitors such as huperzine A, lucid dreaming would also be enhanced since lucid dreaming occurs during REM sleep. Furthermore it would be obvious to employ said methods in individuals wherein REM sleep is shortened since it would be expected that lucid dreaming would also be

decreased since REM sleep is shortened and lucid dreaming occurs during REM sleep. Thus it would be obvious to increase REM sleep in individuals who have shortened REM sleep in order to enhance and intensify REM sleep.

Conclusions

Claims 1, 3-5 and 7-9 are rejected. Claims 2, 6 and 10 are cancelled.. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA R. MCMILLIAN whose telephone number is (571)270-5236. The examiner can normally be reached on Monday-Thursday from 8:30 am- 6:00 pm and every other Friday from 8:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kara R. McMillian/
Examiner, Art Unit 1627

KRM

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627